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09/917,433	07/27/2001	Laurence Lee	P430.12-0002	2032

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EXAMINER	
TSOY, ELENA	

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1762	

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ART UNIT	PAPER

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Commissioner for Patents

This letter is to confirm that finality of the action mailed December 24, 2002 has been withdrawn in favor of non-final rejection mailed April 28, 2003. This letter is a substitute of lost Notice of Withdrawn Action mailed April 25, 2003.

ELENA TSOY
PRIMARY EXAMINER
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Elena Tsoy
Primary Examiner
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/917,433
Filing Date: July 27, 2001
Appellant(s): LEE ET AL.

Z. Peter Sawicki
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 2, 2004

(1) ***Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

(2) ***Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) ***Status of Claims***

The statement A that claims 1-12, 19 and 29-26 are cancelled is incorrect. A correct statement of the status of the claims is as follows:

Claims 1-12, 20-25 had been canceled before filing the Appeal Brief. Claim 19 has been cancelled according to Applicant's request submitted with the Appeal Brief.

(4) ***Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) ***Summary of Invention***

The summary of invention contained in the brief is correct.

The appellant's statement of the issues in the brief is correct.

(6) ***Issues***

The appellant's statement of the issues in the brief is correct.

(7) ***Grouping of Claims***

Appellant's brief includes a statement that claims 1-18, 26-30 stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

4,858,552	GLATT et al	8-1989
3,354,863	REYNOLDS	11-1967
5,632,102	LUY et al	5-1997
4,993,264	CODY et al	2-1991
4,217,851	BIEHL et al	8-1980

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 13-16, 18, 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glätt et al (US 4,858,552) in view of Reynolds (US 3,354,863), further in view of Luy et al (US 5,631,102), and further in view of Cody et al (US 4,993,264).

Glatt et al disclose a fluidized bed apparatus capable of spray coating, and drying pellets of pharmaceutical material (See column 1, lines 27-38; column 2, lines 15-21). The fluidized bed comprises a perforated base through which fluidizing gas flows, a channeling chamber such as a cylindrical rising tube and a spray nozzle (See column 2, lines 54-68; column 3 lines 1-8). In column 3, lines 63-65, the reference teaches that the channeling cylinder may be vertically adjusted to adapt to different process conditions. The reference further teaches that the spray nozzle may also be adjusted vertically to allow for different particle sizes and densities (See column 3, lines 52-56, 66-68; column 4, lines 1-2). Glatt et al dlsclose that the particles are carried upwards through the bed and are deflected outward and carried to the lower inlet area of

the rising tube to allow for the particles to increase in size during the process (See column 3, lines 31-36, 50-53). Glatt et al teach that the particles are loaded into the bed, and then are fluidized by an upward flowing gas (See column 3, lines 22-36). In Figure 1, Glatt et al show. that the spray nozzle is adjusted to form a coating region inside of the cylindrical chamber. Furthermore Glatt et al teach that the circulating fluid allows for drying of the particles during the coating and agglomeration process (See column 3, lines 15-21). The particles are circulated through the fluidized bed several times until the particles have reached the appropriate size (See column 3, lines 50-55). Glatt et al disclose that a multi-medium nozzle, which comprises liquid and gaseous components where the gaseous components atomize the liquid, is used as the spraying means for the coating liquid (See column 6, lines 24-35). Glatt et al disclose that the fluidized spray is used to agglomerate and coat the particles in the fluidized bed (See Abstract). The spraying liquid may be a liquid fat (See column 7, lines 11-14). In column 3, lines 50-68, Glatt et al teach that the liquid sprayer is height adjustable. In Figures 1 and 10, Glatt et al show that the spray nozzle is adjustable below the bottom edge of the cylindrical chamber.

Glatt et al fail to teach positioning the spray nozzle in a non-heat conduction relation to the bottom screen.

Reynolds teaches a method of coating particses with a method ofcoating and drying the coating (See column 1, lines 10-13). The coating apparatus, taught by Reynolds, comprises a cylindrical chamber in the fluidized bed, through which the coating fluid is sprayed, a spray nozzle, which has a coating fluid and an atomizing fluid, and a perforated base through which the fluidizing gas flows (See Figure 1 and column 1, lines 27-54). Reynolds discloses that the particles circulate through the apparatus by flowing upward through the cylindrical coating section and flowing downward in the drying section outside of the cylindrical chamber (See

column 1, lines 55-42; column 2, lines 1 -5). Reynolds discloses that the spray nozzle comprises a coating material and an atomizing fluid and may be positioned above the perforated plate in a non-heat conducting manner or it may be positioned flush with the perforated plate (See Fig. 1; column 5, lines 24-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to position the spray nozzle in the fluidized bed coating/agglomeration apparatus, taught by Glatt et al, above the perforated plate in view of the teaching of Reynolds that placing the nozzle flush with the plate is equivalent to placing it above the perforated plate in a non-heat conducting relation to the perforated plate.

<u>As to the heated liquid line and monitoring a spray liquid line temperature</u>, Glatt et al disclose a fluidized bed coating apparatus, as disclosed above. The reference further teaches that the spraying means may be heated to prevent the liquid from solidifying (See column 6, lines 33-35). Reynolds also discloses a fluidized bed coating apparatus described above. However, neither reference teaches the use of a heated liquid line for maintaining the coating material at a certain temperature.

Luy et al disclose a coating apparatus that is used to coat particulate substrates (See Abstract). The coating apparatus disclosed by Luy et al is a fluidized bed coater that has a spray nozzle that sprays the coating material onto the fluidized particles (See abstract and column 1, lines 11 -16). Luy et al teach that the particles to be coated are fluidized upwards through a coating chamber and deflected outward and carried to the lower inlet area of the coating chamber (See Fig. 1). Luy et al additionally teach that the liquid pumped to the spray nozzle is heated by the heating device that is attached to the liquid line (See Fig. 1 and column 11, lines 13-30). Luy

et al teach that the coating liquid is *maintained at a certain temperature, which is measured by a temperature sensor* (See column 8, lines 33-54).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have heated the liquid line for the fluidized coating apparatus taught by Glatt et al in view of the teaching of Glatt et al to heat the liquid by heating the spraying nozzle and in further view of the teachings of Luy et al to use a heating device to heat the liquid in the liquid line while maintaining the liquid a certain temperature by using a temperature sensor on the spraying nozzle.

<u>As to monitoring a fluidizing gas flow</u>, Glatt et al disclose that the **gas velocities** passing through the perforations can be **changed** *even in the course of the treatment process* so that ***adaptation*** corresponding to the particle size **during treatment** is possible (See column 6, lines 6-9). Therefore, Glatt et al teach *monitoring* a fluidized gas flow.

<u>As to monitoring an inlet air temperature, coating zone temperature and a product temperature</u>, Glatt et al teach that resetting the positions of the elements can preferably take place during the course of processing one load. A device equipped preferentially with a **process control computer** (not shown) can be provided for readjusting the channeling means 5 and/or the rotatable means 7 and/or the spray means 6 and/or the perforations in the base means 4. Thus, with the present invention, ***control*** *as a function of the* ***product*** can take place even **during** the treatment process. Glatt et al further teach that it is desirable when coating with fat, gas feeders introduce in the central inner area, a *gas having a higher temperature than the gas in the outer annular area* (See column 7, lines 6-11). This allows working within the channeling means 5 with an elevated temperature and *maintaining the fat in a liquid state* (See column 7, lines 11-13). An appropriate cooling, desirable when coating with fat, may be provided by the

introduction of cooler air into the outer annular area (See column 7, lines 17-20). In other words, Glatt et al teach *monitoring inlet air temperature* to maintain the fat in a liquid state, and maintaining the temperature of cooler air in the outer annular area to achieve non-sticky product coated with fat, i.e. *monitoring temperature of a (coated) product.*

As to monitoring a product temperature, a spray liquid temperature, a spray nozzle temperature, an atomizing air temperature, a spray liquid line temperature, a coating zone temperature, a fluidizing gas flow, and atomizing gas pressure, Glatt et al also teach that it will be appreciated that the **coating parameters are *selected*** (i.e. *coating parameters* are *monitored*) to provide a coating which is already hardened to the point that plastic molding is possible upon impacting on the underside of the rotatable means 7 (See column 7, lines 14-17). The spraying means 6 can also be **heated** to prevent the spray media from solidifying (See column 6, lines 33-34). However, Glatt et al do not expressly show that *coating parameters* that are monitored are a product temperature, a spray liquid temperature, a spray nozzle temperature, an atomizing air temperature, a spray liquid line temperature, a coating zone temperature, a fluidizing gas flow, and atomizing gas pressure are monitored.

Cody et al teach that pressure, temperature and net volume or mass flow are the normal way of monitoring the state of fluidization within a fluidized bed or while a unit is operating (See column 2, lines 27-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have monitored fluidized bed parameters such as a product temperature, a spray liquid temperature, a spray nozzle temperature, an atomizing air temperature, a spray liquid line temperature, a coating zone temperature, a fluidizing gas flow, and atomizing gas pressure in a process of Glatt et al/in view of Reynolds/in view of Luy et al for coating particles with the

expectation of providing the desired normal coating operation since Cody et al teach that pressure, temperature and net volume or mass flow are the normal way of monitoring the state of fluidization within a fluidized bed or while a unit is operating.

As to claim 29, Glatt et al. do not disclose a method for removing the coated particles from the fluidized bed.

However, Reynolds teaches the use of a product line that removes coated particles from the bottom of the bed during the fluidization process so that the cyiindrical chamber is not removed from the fluidized bed during product removal (Figures 1 and 2 and column 1 lines 40-42, and 51 -53).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to prior aT't for a method of removing the coated particles from the fluidized bed taught by Glatt et al in the absence of a teaching for removing the product particles. and to use ttne product line, in view of the teaching of Reynolds to remove the product particles hvittnotlt disturbing the cylindrical partition within the chamber.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Glatt et al (US 4,858,552) in view of Reynolds (US 3,354,863), further in view of Luy et al (US 5,631,102), further in view of Biehl et al (US 4,217,851), and further in view of Cody et al (US 4,993,264).

Glatt et al, Reynolds and Luy et al are applied here for the same reasons as above.

However, neither reference discloses the diameter-to-height ratio of the cylindrical portion in the fluidized bed.

Biehl et al disclose a fluidized bed coating apparatus that comprises a perforated plate, through which the fluidizing gas flows, a spray nozzle and a cylindrical coating chamber (See Fig. 1 and column 2, lines 47-68). In column 4, lines 50-58, Biehl et al teach that the particles

flow upward through the cylindrical coating chamber, where they are sprayed with coating liquid. In Figure 1, the diameter of the cylindrical chamber appears to be equivalent to the length of the chamber.

It would have been obvious to one of ordinary skill in the art at the time the invention was made in absence of a specific diameter-to-length ratio being disclosed by Glatt et al in view of Reynolds in view of Luy et al to use a ratio equal to one as disclosed by Biehl et al.

As to monitoring fluidized bed parameters, Glatt et al in view of Reynolds in view of Luy et al in view of Biehl et al fail to teach that an inlet air temperature, a product temperature, a spray liquid temperature, a spray nozzle temperature, an atomizing air temperature, a spray liquid line temperature, a coating zone temperature, a fluidizing gas flow, and atomizing gas pressure are monitored.

Cody et al are applied here for the same reasons as above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have monitored fluidized bed parameters such as a product temperature, a spray liquid temperature, a spray nozzle temperature, an atomizing air temperature, a spray liquid line temperature, a coating zone temperature, a fluidizing gas flow, and atomizing gas pressure in a process of Glatt et al/in view of Reynolds/in view of Luy et al/in view of Biehl et al for coating particles with the expectation of providing the desired normal coating operation since Cody et al teach that pressure, temperature and net volume or mass flow are the normal way of monitoring the state of fluidization within a fluidized bed or while a unit is operating.

(11) Response to Argument

Applicants argue that the Examiner has failed to establish a prima facie case

of obviousness because neither the Glatt patent, the Reynolds patent, the Luy patent or the Cody patent disclose monitoring an air inlet temperature, a product temperature, a spray liquid temperature, a spray nozzle temperature, an atomizing air temperature, a spray liquid line temperature, a coating zone temperature, a fluidizing gas flow, and an atomizing gas pressure. The Cody patent simply makes a statement that pressure, temperature, and net volume are normally monitored in a fluidized bed dryer. Nothing in the Cody patent or the other cited references teaches or suggests the monitoring of these process variables.

The Examiner respectfully disagrees with this argument. First of all, the specification as filed fails to show explicitly that *all* recited parameters are being monitored. In "SUMMERY OF INVENTION" of the appeal brief, Applicants refer to page 18, lines 23-28. Since the specification as filed has only 14 pages, the Examiner assumed that Applicants meant page 8, lines 23-28. In lines 23-28 of the page 8, specification discloses maintaining inlet gas temperature, liquid fat temperature, liquid fat flow rate, and other operating parameters.

As was discussed above, Glatt patent discloses maintaining inlet gas temperature, a temperature in a coating chamber which has a spray nozzle (i.e. coating zone temperature, spray nozzle temperature and liquid fat temperature), a product temperature (See column 7, lines 1-20), a fluidizing gas flow (See column 6, lines 4-9). Also Glatt patent teaches "It will be appreciated that the **coating parameters are selected** to provide a coating which is already hardened to the point that plastic molding is possible upon impacting on the underside of the rotatable means 7". Therefore, Glatt patent explicitly teaches *monitoring coating parameters*. Cody et al teach that pressure, temperature and net volume or mass flow are the normal way of monitoring the state of fluidization within a fluidized bed or while a unit is operating (See column 2, lines 27-30).

Therefore, it would be within the level of ordinary engineering skill to monitor claimed particular pressure and temperature parameters, flow rates to achieve normal operation of fluidized bed depending on particular particle to be coated, coating material, etc. in the absence of a showing of criticality of claimed parameters.

Since nowhere in the specification, Applicants show the criticality of chosen parameters, monitoring any operating parameter of a fluidized bed would be within the level of ordinary engineering skill.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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May 20, 2005

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